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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: George Gorodeski)	Examiner: not yet assigned
)	
Serial No.: 10/576,214)	Art Unit: not yet assigned
)	
Filed: April 17, 2006)	Attorney Docket No.: 29519/04004
)	
For: METHOD AND APPARATUS)	
FOR APPLYING MEDICATION)	Confirmation No.: not yet assigned
TO INTERNAL TISSUE)	

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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B forms and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

FOREIGN LANGUAGE DOCUMENTS

☐ In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of a Communication

from a foreign patent office in a counterpart application citing such documents, together with an English-language version of that portion of the Communication indicating the degree of relevance found by the foreign patent office.

- ☐ In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant submits the following explanations:
- ☐ Complete English translations of foreign language documents are being submitted herewith, and therefore no concise explanation for such documents is required.

CERTIFICATION AND FEE PAYMENT INFORMATION

- ☒ The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination under 37 C.F.R. § 1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required. If this is not the case, the patent office is hereby authorized to charge any related fee to **Deposit Account No. 030172, order number 29519/04004.**
- ☐ The present Information Disclosure Statement is being filed thirty days or fewer from a Communication from a foreign patent office and Applicant submits the following Statement Under 37 C.F.R. § 1.704(d). Each item of information contained in the Information Disclosure Statement was cited in a Communication from a foreign patent office in a counterpart application and this Communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☐ The present Information Disclosure Statement is being filed after the later of three months from the application's filing date and mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore Applicant submits the following Statement under 37 C.F.R. § 1.97(e). No fee under 37 C.F.R. § 1.17(p) is required. If this is not the case, the patent office is hereby authorized to charge any related fee to **Deposit Account No. 030172.**
 - ☐ Each item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
 - ☐ No item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable

inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this statement.

- ☐ The present Information Disclosure Statement is being filed (without a Statement under 37 C.F.R. § 1.97(e)) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier). Accordingly, Applicant submits the fee required under 37 C.F.R. § 1.17(p). The fee is being paid in the following manner:
- ☐ A check is attached in the amount of \$_____ as required under 37 § 1.17(p).
- ☐ The patent office is hereby authorized to charge the amount of \$_____ and any related fee to **Deposit Account No. 030172**.

- ☐ The present Information Disclosure Statement is being filed after the mailing of a final Office Action, Notice of Allowance or an action that otherwise closes prosecution in the application, but on or before the payment of the issue fee. Accordingly, Applicant submits the following Statement under 37 C.F.R. § 1.97(e) along with the fee required under 37 C.F.R. § 1.17(p).
- ☐ Each item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

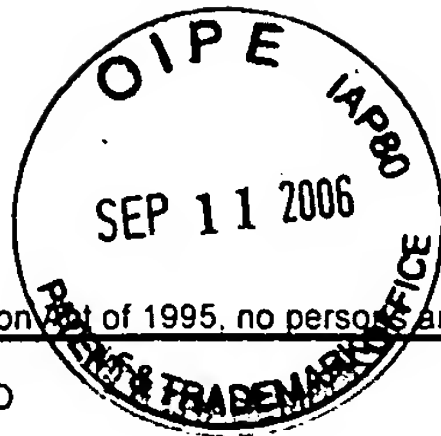
AND, the fee is being paid in the following manner:

- ☐ A check is attached in the amount of \$_____ as required under 37 § 1.17(p).
- ☐ The patent office is hereby authorized to charge the amount of \$_____ and any related fee to **Deposit Account No. 030172**.

Respectfully submitted,

Date: 9/7/06

By: Ken Smith
Kenneth J. Smith, Reg. No. 45,115
Customer No. 24024
(216) 622-8674



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/576,214
Filing Date	April 17, 2006
First Named Inventor	George Gorodeski
Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	29519/04004

Sheet 1 of 14

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 3,797,494	08/09/1971	Zaffaroni	
		US- 4,016,251	04/05/1977	Higuchi et al.	
		US- 4,052,505	10/04/1977	Higuchi et al.	
		US- 4,069,307	01/17/1978	Higuchi et al.	
		US- 4,144,317	03/13/1979	Higuchi et al.	
		US- 4,291,014	09/22/1981	Keith et al.	
		US- 4,321,252	03/23/1982	Keith et al.	
		US- 4,438,139	03/20/1981	Keith et al.	
		US- 4,976,692	12/11/1990	Atad	
		US- 5,027,830	07/02/1991	Koch	
		US- 5,104,377	04/14/1992	Levine	
		US- 5,164,189	03/11/1991	Farhadih et al.	
		US- 5,261,878	11/16/1993	Galindo	
		US- 5,295,984	03/22/1994	Contente et al.	
		US- 5,306,249	04/26/1994	Don Michel	
		US- 5,397,307	03/14/1995	Goodin	
		US- 5,460,610	10/24/1995	Don Michel	
		US- 5,505,701	04/09/1996	Anaya Fernandez de Lomana	
		US- 5,508,045	04/16/1996	Harrison	

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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of 14

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		US- 5,508,045	04/16/1996	Harrison et al.	
		US- 5,510,064	04/23/1996	Koch	
		US- 5,529,782	11/03/1994	Staab	
		US- 5,545,210	08/13/1996	Hess et al.	
		US- 5,554,119	09/10/1996	Harrison et al.	
		US- 5,558,642	09/24/1996	Schweich, Jr. et al.	
		US- 5,562,641	10/08/1996	Flomenblit et al.	
		US- 5,607,691	03/04/1997	Hale et al.	
		US- 5,612,051	03/18/1997	Yue	
		US- 5,624,399	04/29/1997	Ackerman	
		US- 5,656,638	08/12/1997	Gaeta et al.	
		US- 5,674,239	10/07/1997	Zadini et al.	
		US- 5,679,647	10/21/1997	Carson et al.	
		US- 5,703,116	12/30/1997	Gaeta et al.	
		US- 5,707,642	01/13/1998	Yue	
		US- 5,713,861	02/03/1998	Vanarthos	
		US- 5,716,340	02/10/1998	Schweich, Jr. et al.	
		US- 5,749,845	05/12/1998	Hildebrand et al.	
		US- 5,750,134	05/12/1998	Scholz et al.	

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Sheet **3** of **14****U. S. PATENT DOCUMENTS**

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		Number-Kind Code ² (if known)			
		US- 5,760,062	06/02/1998	Gaeta et al.	
		US- 5,762,956	06/09/1998	Chien et al.	
		US- 5,767,278	06/16/1998	Gaeta et al.	
		US- 5,770,613	06/23/1998	Gaeta et al.	
		US- 5,780,045	11/08/1996	McQuinn et al.	
		US- 5,800,374	09/01/1998	Beyersdorf	
		US- 5,804,566	09/08/1998	Carson et al.	
		US- 5,811,410	09/22/1998	Falk et al.	
		US- 5,827,834	10/27/1998	Falk et al.	
		US- 5,830,848	11/03/1998	Harrison et al.	
		US- 5,830,877	11/03/1998	Carson et al.	
		US- 5,830,882	11/03/1998	Falk et al.	
		US- 5,833,974	11/10/1998	Teicher	
		US- 5,849,719	12/15/1998	Carson et al.	
		US- 5,852,002	12/22/1998	Falk et al.	
		US- 5,858,365	01/12/1999	Faller	
		US- 5,863,552	01/26/1999	Yue	
		US- 5,863,936	01/26/1999	Gaeta et al.	
		US- 5,869,539	02/09/1999	Garfield et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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		Number-Kind Code ² (if known)			
		US- 5,877,216	03/02/1999	Place et al.	
		US- 5,902,817	05/11/1999	Jackson et al.	
		US- 5,908,407	06/01/1999	Frazee et al.	
		US- 5,914,314	06/22/1999	Falk et al.	
		US- 5,929,048	07/27/1999	Falk et al.	
		US- 5,932,560	08/03/1999	Falk et al.	
		US- 5,947,991	09/07/1999	Cowan	
		US- 5,962,521	10/05/1999	Jackson et al.	
		US- 5,972,924	10/26/1999	Keep et al.	
		US- 5,980,804	11/09/1999	Koch	
		US- 5,985,847	11/16/1999	Carson et al.	
		US- 5,985,850	11/16/1999	Falk et al.	
		US- 5,985,851	11/16/1999	Falk et al.	
		US- 6,010,530	01/04/2000	Goicoechea	
		US- 6,022,359	02/08/2000	Frantzen	
		US- 6,037,125	03/14/2000	Hasty	
		US- 6,048,544	04/11/2000	Yue	
		US- 6,048,844	04/11/2000	Falk et al.	
		US- 6,054,444	04/25/2000	Jackson et al.	

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		Number-Kind Code ² (if known)			
		US- 6,054,470	04/25/2000	Betageri et al.	
		US- 6,057,104	05/02/2000	Hasty	
		US- 6,069,135	05/30/2000	Falk et al.	
		US- 6,071,707	06/06/2000	Barton et al.	
		US- 6,071,965	06/06/2000	Jackson et al.	
		US- 6,086,610	07/11/2000	Duerig et al.	
		US- 6,103,275	08/15/2000	Seitz et al.	
		US- 6,119,697	09/19/2000	Engel et al.	
		US- 6,121,252	09/19/2000	Jackson et al.	
		US- 6,133,317	10/17/2000	Hart	
		US- 6,139,538	10/31/2000	Houghton et al.	
		US- 6,150,377	11/21/2000	Lyssikatos et al.	
		US- 6,156,784	12/05/2000	Betageri et al.	
		US- 6,166,079	12/26/2000	Follen et al.	
		US- 6,174,687	01/16/2001	Rajotte et al.	
		US- 6,174,872	01/16/2001	Carson et al.	
		US- 6,186,945	02/13/2001	Gardosi	
		US- 6,194,392	02/27/2001	Falk et al.	
		US- 6,197,327	03/06/2001	Harrison et al.	

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		Number-Kind Code ² (if known)			
		US- 6,197,743	03/06/2001	Faller	
		US- 6,246,898	06/12/2001	Vesely et al.	
		US- 6,247,678	06/19/2001	Hines et al.	
		US- 6,264,948	07/24/2001	Wong et al.	
		US- 6,265,609	07/24/2001	Jackson et al.	
		US- 6,268,365	07/31/2001	Betageri et al.	
		US- 6,271,245	08/07/2001	Jackson et al.	
		US- 6,280,425	08/28/2001	Del Guercio	
		US- 6,284,768	09/04/2001	Betageri et al.	
		US- 6,288,046	09/11/2001	Jackson et al.	
		US- 6,294,550	09/25/2001	Place et al.	
		US- 6,294,552	09/25/2001	Lyssikatos et al.	
		US- 6,296,832	10/02/2001	Ruoslahti et al.	
		US- 6,299,598	10/09/2001	Bander	
		US- 6,306,841	10/23/2001	Place et al.	
		US- 6,350,463	02/26/2002	Herman et al.	
		US- 6,352,996	03/05/2002	Cao et al.	
		US- 6,372,742	04/16/2002	Chin et al.	
		US- 6,375,676	04/23/2002	Cox	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	10/576,214
Filing Date	April 17, 2006
First Named Inventor	George Gorodeski
Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	29519/04004

Sheet **7** of **14****U. S. PATENT DOCUMENTS**

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		US- 6,384,022	05/07/2002	Jackson et al.	
		US- 6,391,589	05/21/2002	Olsen et al.	
		US- 6,395,718	05/28/2002	Slusher et al.	
		US- 6,410,595	06/25/2002	Neal	
		US- 6,414,027	07/02/2002	Neal	
		US- 6,420,335	07/16/2002	Weichselbaum et al.	
		US- 6,426,336	07/30/2002	Carson et al.	
		US- 6,429,298	08/06/2002	Ellington et al.	
		US- 6,433,145	08/13/2002	LaFleur et al.	
		US- 6,452,014	09/17/2002	Akama et al.	
		US- 6,464,200	10/15/2002	Hines et al.	
		US- 6,469,016	10/22/2002	Place et al.	
		US- 6,472,434	10/29/2002	Place et al.	
		US- 6,472,512	10/29/2002	LaFleur et al.	
		US- 6,475,164	11/05/2002	Gombrick et al.	
		US- 6,475,753	11/05/2002	Ruben et al.	
		US- 6,476,195	11/05/2002	Komatsoulis et al.	
		US- 6,478,656	11/12/2002	Khoury	
		US- 6,479,258	11/12/2002	Short	

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Sheet 9

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NON PATENT LITERATURE DOCUMENTS

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		Levy S et al "A comparison of the skin permeation of three topical .5% fluorouracil formulations with that of a 5% formulation" Clinical Therapeutics vol 23 no 6 2001 pg 901-7	
		International Search Report from PCT/US04/034782.	
		Maiman, M., et al., "Vaginal 5-Fluorouracil for High-Grade Cervical Dysplasia in Human Immunodeficiency Virus Infection: A Randomized Trial", Obstetrics & Gynecology, vol. 94	
		(continued from line above) no. 6, December 1999, pgs. 954-961.	
		Sidhu, S.K., et al, "A randomised controlled trial evaluating a novel cytotoxic drug delivery system for the treatment of cervical intraepithelial neoplasia", British Journal	
		(continued from line above) of Obstetrics and Gynaecology, Feb. 1997, vol. 104, pgs. 145-149.	
		Blanco, M.D. et al., "Release of 5-fluorouracil from poly(acrylamide-co-monopropyl itaconate) hydrogels", Journal of Chromatography B, 680, 1996, pgs. 243-253.	
		Woolfson, A.D., et al., "Autoradiographic Imaging of the Distribution of 5-Fluorouracil Through Cervical Tissue Following in Vitro Surface Application of a Bioadhesive	
		(continued from line above) Cervical Patch, Pharmaceutical Research, vol. 12, no. 5, 1995, pgs. 676-681.	
		Stornes, I., et al., "A Phase II Trial of Ifosfamide, 5-Fluorouracil, and Leucovorin in Recurrent Uterine Cervial Cancer", Gynecologic Oncology, 55, 123-125, 1994.	

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Sheet	10	of	14	Attorney Docket Number	29519/04004

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		Woofson, A.D., et al., "Liquid Scintillation Spectrometry of 5-Fluorouracil in Cervical Tissue Following in Vitro Surface Application of a Bioadhesive Cervical Patch",	
		(continued from line above) Pharmaceutical Research, vol. 11, no. 9, 1994, pgs. 1315-1318.	
		Kirwan, P. "Topical 5-fluorouracil in the treatment of vaginal intraepithelial neoplasia", British Journal of Obstetrics and Gynaecology, Mar. 1985, vol 92, pgs 287-291.	
		Pride GL et al "Topical 5-Fluorouracil Treatment of Transformation Zone Intraepithelial Neoplasia of Cervix and Vagina" Obstetrics & Gynecology vol 60 no 4 10/1982 pgs 467-472	
		Sporn, MB, et al., "Cervical Dysplasia Regression Induced by All-trans-Retinoic Acid", Journal of the National Cancer Institute, vol 86, no 7, 04/06/1994, pgs. 476-477.	
		Graham, V., et al., Clinical Investigation "Phase II trial of B-All-trans-Retinoic acid for cervial intraepithelial neoplasia delivered via a collagen sponge and cervical cap"	
		(continued from line above) The Western Journal of Medicine, August 1986, 145, 2, pgs. 192-195.	
		Weiner, S.A., et al, "A phase I trial of topically applied trans-retinoic acid in cervical dysplasia-clinical efficacy", Investigational New Drugs 4: 1986, pgs. 241-244.	
		Peng, Y-M, et al, "Cervical tissue uptake of all-trans-retinoic acid delivered via a collagen sponge-cervical sap delivery device in patients with cervical dysplasia",	
		(continued from line above) Investigational New Drugs 4: 245-249, 1986, pp. 245-249.	

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		Mayskens Jr, FL et al "A Phase I Trial of B-all-trans-Retinoic acid delivered via a collagen sponge and a cervical cap for mild or moderate intraepithelial cervical neoplasia"		
		(continuned from line above) JNCI, vol. 71, no. 5, Nov. 1983, pgs. 921-925.		
		Surwit, EA et al., "Evaluationi of topically applied trans-retinoic acid in the treatment of cervical intraepithelial lesions", Am. J. Obstet. Gynecol. 08/01/1982 pgs. 821-823		
		Formelli, F., Letter to the Editor, "Correspondenfe re: M. Follen et al., A Randomized Clinical Trial of 4-Hydroxyphenylretinamide for Hlgh-Grade Squamous Intraepithelial		
		(continued from line above) Lesions of the Cervix", Clinical Cancer Research, vol. 8, May 2002, pgs. 1310-1312.		
		Follen, M. et al., "A Randomized Clinical Trial of 4-Hydroxyphenylretinamide for High-Grade Squamous Intraepithelial Lesions of the Cervix", Clinical Cancer Research		
		(continued from line above) vol. 7, November 2001, pgs. 3356-3365.		
		Diaz-Arrastia, C., et al., "Clinical and Molecular Responses in High-Grade Intraepithelial Neoplasia Treated with Topical Imiquimod 5%", Clinical Cancer Research, vol. 7		
		(continued from line above) October 2001, pgs. 3031-3033.		
		Keefe, K.A. et al., "A Randomized, Double Blind, Phase III Trial Using Oral B-Carotene Supplementation for Women with High-Grade Cervical Intraepithelial Neoplasia",		

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		(continued from previous page) Cancer Epidemiology, Biomarkers & Prevention, vol. 10, October 2001, pgs. 1029-1035.	
		Comerci, Jr., JT, et al., "Induction of Transforming Growth Factor B-1 in Cervical Intraepithelial Neoplasia in Vivo after Treatment with B-Carotene", Clinical Cancer	
		(continued from previous line) Research, vol. 3, February 1997, pgs. 157-160.	
		Torne, A., et al., Letters to the Editor "Correspondence re: A. Manetta et al., B-Carotene Treatment of Cervical Intraepithelial Neoplasia: A Phase II Study", Cancer	
		(continued from previous line) Epidemiology, Biomarkers & Prevention, vol. 6, August 1997, pgs. 655-656.	
		Monk BJ et al "Photodynamic Therapy Using Topically Aplied Dihematoporphyrin Ether in the Treatment of Cervical Intraepithelial Neoplasia" Gynecologic Oncology 64, 1997, 70-75	
		Snoeck, R., et al., "Cidofovir, a new approach for the treatment of cervix intraepithelial neoplasia grade III (CIN III)", Journal of Medical Virology 60: 2000, 205-209.	
		Barnett, AA, et al., "A randomised, double-blind, placebo-controlled trial of photodynamic therapy using 5-aminolaevulinic acid for the treatment of cervical intraepithelial	
		(continued from line above) neoplasia", Int. J. Cancer: 103, 2003, pgs. 829-832.	
		Wierrani F, et al "5-Aminolevulinic Acid-Mediated photodynamic therapy of intraspithelial neoplasia and human papillomavirus of the uterine cervix-a new experimental approach"	

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		(continued from line above) Cancer Detection and Prevention, 23(4) 1999, pgs. 351-355.	
		Hillemanns, P., et al, "Photodynamic therapy in women with cervical intraepithelial neoplasia using topically applied 5-aminolevulinic acid", Int. J. Cancer 81 1999, 34-38.	
		Katesmark, M et al, "A pilot study of the efficacy and tolerability of initralesional recombinant human beta-interferons in cervical intraepithelial neoplasia", Ann. Acad Med	
		(continued from line above) Singapore vol. 28, no. 6, 1999, pgs. 775-777	
		Hsu, C., Letters to the Editor, "Evaluation of interferon treatment of cervical intraepithelial neoplasia", Acta Cytologica, vol 29, no. 2, Mar-Apr 1985, pgs 192-193	
		Mitchell, MF, et al, "Phase I dose de-escalation trial of a-difluoromethylornithine in patients with grade 3 cervical intraepithelial neoplasia", Clinical Cancer Research,	
		(continued from line above) vol. 4, February 1998, pgs. 303-310.	
		Teshima, H et al "Treatment of genital condyloma acuminiatum and vaginal intraepithelial neoplasia (VAIN) with topical idoxuridine and acrarubicin", Acta Obst Gynaec Jpn, vol.	
		(continued from line above) 46, no. 10, 1994, pgs. 1065-1068.	
		Bagloglu, E et al, "An invitro investigation for vaginal bioadhesive formulations: bioadhesive properties and swelling states of polymer mixtures" II Farmaco 58, 2003, 391-396	

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		Hodgson, DE, "Shape Memory Alloys", 12 pgs. printed on 10/6/2003 from http://www.sma-inc.com/SMAPaper.html .	
		Machida, Y, et al "Preparation and phase II clinical examination of topical dosage forum for treatment of carcinoma colli containing bleomycin with hydroxypropyl cellulose"	
		(continued from line above) Chem Pharm. Bull, vol. 27, no. 1, 1979, pgs. 93-100.	
		Woolfson, AD, et al, "Bioadhesive cervical patch delivery system for the treatment of cervical intraepithelial neoplasia", PDD 7243 paragraph, study Ulster Cancer Foundation.	
		Strickland, J et al, "Cervical Dysplasia", March 2000, from http://www.catie.ca/facts.nfs/ website printed on 08/04/2003, 5 pgs.	
		Two page brochure, New RepHresh Vaginal Gel, 2002, printed U.S.	
		Noveon Pharmaceutical Polymers booklet, bulletins 1-21, January 2002, 202 pgs.	
		Meyskens, Jr., FL, et al., "Enhancement of Regression of Cervical Intraepithelial Neoplasia II (Moderate Dysplasia) with topically applied All-trans-retinoic acid: a	
		(continued from line above) randomized trial", Journal of the National Cancer Institute, vol. 86, no. 7, April 6, 1994, pgs. 539-543.	
		Manetta, A et al., "B-Carotene Treatment of cervical intraepithelial neoplasia: a phase II study", Cancer Epidemiology, Biomarkers & Prevention, pgs. 929-932, vol 5, 11/1996.	

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